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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/790,043	01/28/1997	DAVID PAYNE	GM50005	9942

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EXAMINER

PRIEBE, SCOTT DAVID

ART UNIT PAPER NUMBER

1632

DATE MAILED: 04/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/790,043

Applicant(s)

PAYNE ET AL.

Examiner

Scott D. Priebe, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 Dec. 2004 & 28 Jan. 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 61-68 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 61-68 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>20050106</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submissions filed on 12/27/04 and 1/28/05 have been entered.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. In the claims filed 4/14/04, which were finally rejected, there were two claims labeled claim 63. One of these has been relabeled as claim 68.

The arguments presented in both the submissions of 12/27/04 and 1/28/05 appear to be identical.

Priority

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application); the disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

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Provisional application 60/024,845 does not disclose instant SEQ ID NO: 1 and SEQ ID NO: 2, to which the instant claims are directed. The nucleotide sequence disclosed in the '845 application comprises a sequence, nucleotides 281-1050, that are similar but not identical to instant SEQ ID NO: 1. The nucleotides 1041-1050 of the sequence in the '845 application are CAATTAATAN, whereas the last 11 nucleotides of instant SEQ ID NO: 1 are CAATTAAATAA. The amino acid sequence disclosed in the '845 application appears to comprise the amino acids 1-255 of instant SEQ ID NO: 2, but does not comprise the C-terminal Lys residue (a.a. 256) of instant SEQ ID NO: 2, and instead comprises Asn at amino acid 256 followed by 36 additional amino acids. Consequently, the effective filing date of the instant application is its actual filing date of 1/28/97, not that of the '845 application.

Applicant's arguments filed 12/27/04 and 1/28/05 have been fully considered but they are not persuasive. Applicant admits that the provisional application does not disclose instant SEQ ID NOs: 1 and 2, but rather discloses sequences that are similar to them. Contrary to Applicant's assertion that instant SEQ ID NO: 2 differs by a single amino acid at the C-terminus from SEQ ID NO: 2 of the provisional application, these two sequences differ by 37 amino acids. In addition to a substitution difference, the sequence of the provisional application has an additional thirty-six C-terminal amino acids that are not present in instant SEQ ID NO: 2. SEQ ID NO: 2 of the provisional is 292 amino acids in length and comprises 255 amino acids in common with instant SEQ ID NO: 2. Instant SEQ ID NO: 2 has 87.3% sequence identity ($255/292 \times 100$) with SEQ ID NO: 2 of the provisional application as the reference sequence (i.e. viewing the analogous genus from the perspective of the provisional application). Consequently, instant SEQ ID NO: 2 is not embraced by a polypeptide that is 95% identical to SEQ ID NO: 2 of the

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provisional application. While the genus of sequence being claimed now by reference to instant SEQ ID NOs: 1 and 2 may substantially overlap the analogous genus described in the '845 provisional application, it is not identical due to the differences between instant SEQ ID NOs: 1 and 2 and SEQ ID NOs: 1 and 2 of the provisional application.

Claim Rejections - 35 USC § 112

Claims 61-68 remain rejected under 35 U.S.C. 112, first paragraph, for the reasons of record set forth in the Office action of 6/25/04 because the specification, while being enabling for an isolated nucleic acid sequence comprising a nucleotide sequence that encodes a polypeptide that reduces crotonyl-CoA or crotonyl-ACP and comprises an amino acid sequence either identical to SEQ ID NO: 2, or differing from SEQ ID NO: 2 by substitution, insertion or deletion of a single amino acid, does not reasonably provide enablement for a nucleotide sequence encoding a polypeptide that reduces crotonyl-CoA or crotonyl-ACP and differs from SEQ ID NO: 2 by insertion, deletion or substitution more than one amino acid. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Applicant's arguments filed 12/27/04 and 1/28/05 have been fully considered but they are not persuasive. Applicant points out that breadth alone is not a proper test for compliance under 35 USC 112, first para. However, the rejection is not based simply on the breadth of the claims.

Applicant points out that there is no requirement that all specific embodiments of the claimed invention be described. However, the instant specification discloses only one embodiment readable on the claimed subject matter – a polypeptide comprising the amino acid

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sequence of SEQ ID NO: 2. Part of the grounds for rejection were that there are at least 3×10^{35} or 300,000,000,000,000,000,000,000,000,000 amino acid sequences that differ from SEQ ID NO: 2 by up to the 12 amino acid substitutions permitted by the claims. The specification provides no guidance as to which of these differing from SEQ ID NO: 2 would be expected *a priori* to read on the claim, i.e. would reduce crotonyl-CoA or crotonyl-ACP.

Applicant argues that one could use the assay for reduction of crotonyl-CoA or crotonyl-ACP that is disclosed in the specification to screen structural variants. Whether one of skill in the art could make these structural variants for testing for their enzymatic activity is not the issue. The issue is whether the specification informs one of skill in the art how to make a polynucleotide that encodes a polypeptide that one would expect to reduce crotonyl-CoA or crotonyl-ACP without having to hunt for them among more than 300,000,000,000,000,000,000,000,000,000 different polypeptides.

Claim Rejections - 35 USC § 102

Claims 61-68 remain rejected under 35 U.S.C. 102(e) as being anticipated by Kunsch et al. US 6,593,114, which claims priority through US application 08/781,986, filed 1/3/97, for the reasons of record set forth in the Office action of 6/25/04.

Applicant's arguments filed 12/27/04 and 1/28/05 have been fully considered but they are not persuasive. Applicant argues that Kunsch is not prior art since the instant application has priority to the '845 provisional application. However, as indicated above, the instant application is not entitled to the benefit of priority to the provisional application under 35 USC 119(e).

Consequently, the effective filing date of 1/3/97 of the '114 patent qualifies the patent as prior art to the instant application, the effective filing date of which is 1/28/97.

Double Patenting

Claims 61-68 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6,432,670 for the reasons of record set forth in the Office action of 6/25/04. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims embrace the subject matter claimed in the patent.

Applicant requests that this rejection be held in abeyance until indication of allowable subject matter. This is not a proper reply to the rejection. However, in light of the Notice of Non-responsive Amendment filed 1/12/05 directed to a different issue, the Examiner has chosen not to issue a second Notice of Non-responsive Amendment concerning this issue. A proper response to this rejection would be for example, arguments traversing the rejection, amending the claims, or the filing of a terminal disclaimer or a statement of intent to do so if the claims are otherwise allowable.

Conclusion

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action

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after the filing of a request for continued examination and the submission under 37 CFR 1.114.

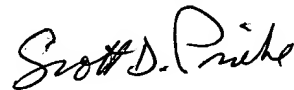
See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott D. Priebe, Ph.D. whose telephone number is (571) 272-0733. The examiner can normally be reached on M-F, 8:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Scott D. Priebe, Ph.D.
Primary Examiner
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